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A Special Rule for Compound Protection for DNA-sequences – Impact of the ECJ “Monsanto” decision on Patent Practice

Jan B. Krauss* and Toshiko Takenaka**

I. Introduction

On October 29, 2010, the U.S. Department of Justice filed an amicus brief in the *Myriad* case, an appeal from the U.S. District Court for the Southern District of New York in which all asserted claims of controversial gene patents were found invalid.¹ The brief highlighted a stark contrast between the positions of different government sectors in the same jurisdic-

tion, the United States, with respect to the scope of patent eligible subject matter under 35 USC §101 and the interpretation of that statute by the Supreme Court. The brief urged the appellate court to invalidate claims relating to an isolated DNA sequence because it is a natural phenomenon, while acknowledging the United States Patent and Trademark Office (“USPTO”) examination practice granting patents on such claims.

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1 *Ass’n for Molecular Pathology v. United States PTO*, 702 F. Supp. 2d, 181, 94 USPQ2d 683 (S.D.N.Y. 2010).

It is even more challenging for courts and patent offices in different jurisdictions to take identical positions on interpreting the same statute. The European Union ("EU") and its member states enacted the Biotech-Directive ("Directive") more than a decade ago to clarify and harmonize the patentability and scope of protection for biotechnological inventions under national law.² The member states, such as Germany and the Netherlands, consequently had to revise their national patent laws in order to implement the Directive requirements. Although not all members of European Patent Convention ("EPC") are members of the EU and the European Patent Organization, the organization of EPC members is a separate institution from the EU. The EPC has also been revised to incorporate patentability-related articles of the Directive.³ Because of this, patent offices and courts in EU member states have to interpret and apply the language of the Directive when dealing with biotechnological inventions. However, interpretation of the language in the Directive by national legislators and courts has not been uniform. Implementing the Directive in national laws is controversial because patent professionals and scholars disagree as to what the obligations are under the Directive. As a result, important issues such as the question of whether DNA-sequences as natural compounds are patent eligible, the meaning of "gene patents" and "biological material," and the extent of the scope of protection for

patents on genes and DNA sequences remains unclear.

In Europe, the recent decision by the European Court of Justice (ECJ) in *Monsanto v. Cefetra*⁴ ("*Monsanto*") has triggered extensive debates among European patent professionals and scholars. In *Monsanto*, the ECJ interpreted Article 9 of the Directive when deciding on infringement of a plant-based gene patent. Although the asserted claims are directed to an isolated DNA sequence, *i.e.*, a compound without any limitation in view of its function or purpose, the ECJ made it clear that a compound infringes the patent only if the compound performs the function or purpose disclosed in the specification. Accordingly, the ECJ applied a "function-limited" or "purpose-bound" protection for DNA sequence patents, even when a claim does not include any limitation regarding the function or purpose that the sequence performs.

At first sight, *Monsanto* only deals with the scope of protection for a DNA sequence patent, *i.e.* legal issues in determining infringement. Since the EPC applies only to the patent granting procedure, the impact should be limited to patent enforcement in national courts. However, some aspects of ECJ's discussions in *Monsanto* may also result in a significant impact on the patentability of a claim directed to a DNA-sequence as a compound. Such impact extends to not only national level but also international level including both EU and EPC member states. In other words, EU member states must take the ECJ case law into account because of their

2 Directive 98/44/EC of the European Parliament and the Commission of July 6, 1998 regarding the legal protection of biotechnological inventions, OJ L 213 of July 30, 1998, p. 13-21

3 See EPC 2000: Rules 26 to 29

4 See European Court of Justice (ECJ) Decision of July 6, 2010; Case C-428/08

EU membership and ratification of the Directive. ECJ Case Law also has a significant influence on EPC member states that are non-EU member states because Rule 26 (1) EPC requires interpretation of the EPC in view of the Directive.⁵

This article will analyze the *Monsanto* decision, and criticize the ECJ's interpretation of Article 9 as being incomplete, in particular for failing to take account of all articles and recitals in the Directive relating to the scope of protection. It will argue that applying the concept of a function-limited protection is unnecessary if a claim directed to an isolated DNA sequence is properly interpreted. It will also discuss the possible impact not only on the protection scope but also on the patentability of gene patents.

II. Background and Facts in Monsanto

Monsanto is the owner of European Patent EP 0 546 090 ("090 Patent") directed to an isolated DNA-sequence, which renders a soybean plant resistant against the herbicide glyphosate when it is introduced into the plant.⁶ The specification of the '090 Patent discloses how the isolated DNA sequence functions in order to provide the resistance to soybean plants. Such herbicide resistant soybean plants are called Roundup Ready® or RR ("RR"), and are commonly used in agriculture.

Although Monsanto secured patent protection in EPC countries, including the Netherlands, through the '090 patent, Monsanto did not have a corresponding patent in Argentina. RR soybeans were harvested and processed into meal in Argentina, and was then subsequently imported into Europe by Cafetra and Toepfer. While the imported RR soybean meal contained the patented DNA-sequence, it could no longer function as a resistance marker and was merely contained as a "residue" in the soybean meal. Nevertheless, Monsanto initiated an action to block the import of the meal into the European Union. Monsanto filed for an injunctive relief, asserting infringement of the '090 Patent at the Court of The Hague (Rechtbank's-Gravenhage) when the RR soybean meal arrived in the Netherlands.

The Court of The Hague found that the imported RR soybean meal no longer performs the herbicide resistant function, and consequently held that the meal would not infringe the '090 Patent. The Hague Court rejected Monsanto's argument that mere presence of the patented DNA sequence in the meal would be sufficient to uphold a claim of infringement as long as the sequence had performed the herbicide resistance function in the past and could perform the function again after it would have been isolated from the soybean meal and transferred into a living material. The Hague Court interpret-

⁵ The decision was consequently published in the OJ EPO 8-9/2010, pages 428 to 447

⁶ Claims 1, 5 and 6 of the granted EP patent read (Please note that only the scope of Claim 6 was referred to ECJ for interpretation of Article 9 of the Directive):

1. An isolated DNA sequence encoding a class II EPSPS enzyme, said enzyme being an EPSPS enzyme having a K_m for phosphoenolpyruvate (PEP) between 1-150 μ M and a $K_i(\text{glyphosate})/K_m(\text{PEP})$ ratio between 3-500, which enzyme is capable of reacting with antibodies raised against a class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, and SEQ ID NO:5.
5. An isolated DNA sequence encoding a protein which exhibits EPSPS activity wherein said protein is capable of reacting with antibodies raised against a Class II EPSPS enzyme, selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.
6. The DNA sequence of Claim 5 wherein said antibodies are raised against a Class II EPSPS enzyme of SEQ ID NO:3.

ed the extent of patent protection for biotechnological inventions under Article 9 of the Directive and the Dutch Patent Law, Article 53a(3)⁷ which corresponds to Article 9.⁸ The court concluded that the DNA sequence at stake must perform the expected function, although it does not continuously have to perform the function in cases where it is necessary to "activate" the function of a sequence using certain conditions, such as heat, dryness, or disease.

However, the Court of The Hague was not sure if the language in Article 9 of the Directive would be sufficiently clear to support the function-limited protection as applied. In order to avoid a conflict with the Directive, the Court stayed the infringement proceeding and referred four questions to the EPJ.⁹ Out of the four questions, the question regarding the appropriateness of the function-limited protection is most significant as an issue with a significant impact on the value of patents covering DNA sequences. The Hague Court also asked whether EU

member states could provide an absolute compound protection for DNA sequence patents regardless of the function of the sequence in case the ECJ followed the concept of function-limited protection, and whether the function-limited protection would apply also to DNA sequence patents which were issued before the effective date of the Directive.

In the EU court system, an Advocate-General is assigned to each case for conducting research on legal issues involved in the case. After conducting the necessary research, the assigned Advocate-General publishes his or her opinion in favor of a certain outcome before the court issues its judgment. In *Monsanto*, an opinion was authored by Advocate-General Mengozzi, and issued on March 9, 2010.¹⁰ He focused on the verb tense in Article 9 of the Directive and concluded that the scope of protection for a patent on an isolated DNA sequence should be limited by the function as described in the specification in the context of industrial applicability.¹¹

7 Article 53(a) of Dutch Patent Law reads:

1. In respect of a patent on a biological material possessing specific characteristics as a result of the invention, the exclusive right shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
2. In respect of a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention, the exclusive right shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
3. In respect of a patent on a product containing or consisting of genetic information, the exclusive right shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function ...'

8 Article 9 of the Directive reads: "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material save as provided in Article 5(1) in which the product is incorporated and in which the genetic information is contained and performs its function."

9 C-428/08, Reference for a Preliminary Ruling from the Rechtsbank's-Gravenhage (Netherlands) of 29 September 2008, OJ C 313 of 06.12.2008, p.16 (2008).

10 C-428/08, Opinion of Advocate General, available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=Submit&numaff=C-428/08>

11 Article 52(1) EPC requires that European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. Further, Rule 29(3) EPC requires that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application (at the time of filing).

III. ECJ Decision: Interpretation of Article 9 of Directive

The ECJ agreed with the Advocate-General and upheld The Hague court's interpretation of Article 9.¹² In doing so, the Court also relied on the present verb tense in Article 9 of the Directive, which reads "the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all materials save as provided in Article 5(1), in which the generic information is contained *and* performs its function" (emphasis added). With respect to genetic information, such as the isolated DNA sequence covered by the '090 patent, patent protection only extends to a material (here, the plant) which contains the genetic information *only* when the information performs the function of the invention; in *Monsanto* the function is protecting the material (plant) from the effect of herbicide.¹³ Because the gene in the RR soybean meal no longer performs the function of the invention, i.e. the herbicide resistance effect, the protection of '090 Patent does not extend to the soybean meal. To claim protection under Article 9 of the Directive for a material, it would be insufficient that the genetic information, such as an isolated DNA in the material, once had performed the function of invention in the past (i.e., in the living soybean-plant.) It would also be insufficient that

the genetic information would/could resume the function of the invention if it is isolated from the material that the patent protection is asserted against, and introduced into a new material, such as a living organism. In the latter case, the new material would be different from the material that the patent protection is asserted against. Therefore, the patent owner of the genetic information may enforce the patent under Article 9 only with respect to the new material.¹⁴

As a result, the ECJ interpreted the scope of protection of Claim 6 of the '090 patent directing at a DNA sequence as a compound narrower than its literal claim scope. Such restrictive interpretation for a compound claim is, nevertheless, clearly in conflict with the current case law of many EPC member states such as Germany.¹⁵ Article 69 EPC makes clear that the claims determine the extent of patent protection by using the description and drawings as tools for interpretation.¹⁶ In *Monsanto*, the asserted claims are directed to a DNA sequence compound without any limitation on the function that the sequence performs, and thus the compound must be protected *independently* from its function.¹⁷

Monsanto tried to distinguish the literal protection for a patented DNA sequence as such as provided by Article 1(1) of the Directive¹⁸ from the extended

12 C-428/08 Judgment of the Court (Grand Chamber), 6 July 2010, OJ C 234, 28.08.2010, 7 (2010) (*Monsanto* ECJ Judgment)

13 See *id.* paragraph 36.

14 See *id.* paragraph 39.

15 Such as, for example, in the decisions of the Federal Court of Justice (BGH), *Imidazoline*, GRUR 1972, 541, *Antivirussmittel* GRUR 1987, 794, and recently *Mehrgangnabe*, GRUR 2008, 779. There is no case-law of the BGH specifically related to DNA sequences.

16 Article 69(1) EPC reads: "The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

17 But see *Tilman*, GRUR 2004, 561, 564

18 Which reads: "Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive."

protection for a material including such DNA sequence under Article 9, and argued that with respect to the DNA sequence in the accused soybean meal the former protection would be relevant.¹⁹ It emphasized that the scope of protection for a DNA sequence should be absolute regardless of the function of the invention. When rejecting this argument, the ECJ relied on Recital 23 in the preamble of the Directive.²⁰ Recital 23 makes clear that DNA sequences contain technical information and thus are patentable only when the DNA performs a function. The Court also relied on Recital 24, which basically requires a description of a function in the specification to support industrial applicability if a claim is directed to a sequence or partial sequence of gene and that sequence is used to produce a protein or part of a protein.²¹ Because the patentability of a DNA sequence under the Directive depends on the description of the function that the sequence performs, the ECJ concluded that the patent protection for the sequence should be available *only* if the sequence performs the function.²² Otherwise, the function-related limitation ("the genetic information is contained *and* performs its function") included in Article 9 with respect to the extension of the protection to a material containing the genetic information would become meaningless.²³ Monsanto's interpretation would provide protection to a material as long as the sequence is contained in the material regardless of the

function, which clearly would contradict the condition in Article 9.

In denying Monsanto's argument, the ECJ did not clearly distinguish the literal protection and the extended protection of a patented DNA sequence. It justified the function limited protection in terms of patentability of DNA sequences. Accordingly, this interpretation may mislead patent professionals and national legislators that the ECJ created a general rule that the patent protection is available for a DNA sequence only if the DNA performs the function that is disclosed to support industrial applicability regardless of being in an isolated form or being incorporated in a biological material. However, as will be discussed below, patent protection should be available regardless of function described in the specification if the accused product is a DNA sequence in an isolated form and the asserted claim literally covers the sequence.

IV. Analysis of the Interpretation of the ECJ

1. Failure to Interpret Article 9 in Context of the Directive's Structure

In order to analyze the interpretation of the ECJ, it is helpful to first take a look at the overall structure of the Directive. Since Article 9 is part of Chapter II of the Directive entitled "Scope of Protection,"

¹⁹ Monsanto ECJ Judgment *supra* note 12, paragraph 41.

²⁰ Recital 23 reads: "Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;"

²¹ Recital 24 reads: "Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs."

²² Monsanto ECJ Judgment *supra* note 12, paragraph 45.

²³ Monsanto ECJ Judgment *supra* note 12, paragraphs 46 and 47.

and Chapter II further includes Articles 8, 10, and 11 in addition to Article 9, Article 9 should be interpreted in the context of the other Articles in Chapter II. However, the ECJ did not pay much attention to the structure and these other Articles.

Article 8 (1) of the Directive also provides an *extension* of the patent protection with respect to a biological material that has specific characteristics resulting from the invention. This protection is available if the material is derived from the material of the invention by propagation or multiplication and the derived material possesses the same characteristics as those of the material of the invention. Article 8 (2) also provides an *extension* of the patent protection with respect to a process for enabling biological material to have specific characteristics. The scope of a process patent producing the biological material extends to a biological material directly obtained by the patented process. In addition, such scope also extends to any other biological material derived from the material that is directly obtained by the patented process through propagation or multiplication as long as the other material has the same characteristics given by the patented process.²⁴

As discussed above, Article 9 also provides an extension of protection. This protection applies to a patent on a product containing genetic information. This protection is available for a biological material if the material contains genetic information and such information performs its function.

In contrast, Article 10 provides a *limitation* of the extended protection under the exhaustion doctrine. Even if a biological material falls into the extended protection under Article 8 or 9, the protection is not available where (1) the material is legally placed by the patent owner or his or her licensees on the market in the territory of an EU-Member State and (2) the propagation or multiplication of the material necessarily results from the application for which the biological material was marketed unless the material is subsequently used for other propagation or multiplication. Article 11 also relates to a *limitation* of the protection under Article 8 and 9 with respect to the farmers privilege under the EU Directive for plant varieties.²⁵

None of these provisions deals with the literal protection directed to a DNA sequence in isolated form. Therefore, these provisions use the verb "extend" to describe an expansive protection which is *added* to the literal protection. Thus, the ECJ should have clarified that the additional limitations in these provisions apply to only the expansive protection provided in these provisions when it interpreted Article 9.

2. Improper Importation of Patentability Rule into Protection Scope

Instead of the Articles in Chapter II, the ECJ went to cite Recitals 23 and 24, and Article 5(3) in Chapter I of the Directive entitled "Patentability."²⁶ Although the

²⁴ See Article 64(2) EPC and 35 U.S.C. 271(g)

²⁵ European Commission Council Regulation No. 15/2008 of 20 December 2007 on Community plant variety rights, OJ EU 11 January 2008, OJEU L8/2

²⁶ Monsanto ECJ Judgment *supra* note 12, paragraphs 43 and 44.

effect of recitals in EU legislations is unclear,²⁷ the ECJ heavily relied on the Recitals when it interpreted Article 9. As the ECJ expressly acknowledged, these Recitals and Article 5(3) both relate to *patentability* of DNA-sequences instead of the scope of protection.

The ECJ emphasized the requirements with respect to the function under Recital 23 and Recital 24: a DNA sequence must indicate a function to meet the condition of patent eligibility, and said function must be described in the specification to meet the condition of industrial applicability if the sequence is used to produce a protein. In light of Recitals 23 and 24, the ECJ then interpreted Article 5(3), stating that patent protection is available for DNA sequences only if a function performed by the sequence is clearly disclosed in the patent specification. Because the Directive makes it clear that patent protection of a DNA sequence depends on the disclosure of a function performed by the DNA sequence, the ECJ concluded that no patent protection should be available for a DNA that cannot perform the function "for which the sequence was patented."²⁸ This "loss of protection" was then transferred to the infringement analysis.

3. ECJ's Incomplete Analysis and Confusing Interpretation

Not only was the ECJ's analysis improper by relying on patentability related recitals, but also its analysis of the recitals was incomplete because the ECJ failed to

examine Recital 22 that also relates to patentability of a DNA sequence. Recital 22 first acknowledges the controversy surrounding patenting full and partial DNA sequences among EU member states. Despite of such controversy, Recital 22 confirms the patentability of DNA sequences, and requires the member states to apply the same criteria of patentability (*i.e.*, novelty, inventive step, and industrial applicability) to the sequences as well as subject matter in other areas of technology, even though the last sentence of the recital emphasizes that the original application must include a description to support industrial applicability, thereby creating special rules for sequences. In short, Recital 22 of the Directive *prohibits* any additional requirements for patentability.

Second, regarding Recital 23 on which ECJ relied for its interpretation, there are some different nuances in different language versions of the recital, which nevertheless result in a significant impact on its interpretation and thus introduce an ambiguity with respect to what is meant by the function. In the English version, the wording of recital 23 reads: "Whereas a mere DNA sequence without indication of a function does not contain any *technical information* and is therefore not a patentable invention" (emphasis added.) The term "any technical information" is translated into Dutch: "geen technische informatie" (no technical information). In contrast, the German version of Recital 23 reads: "Ein einfacher DNA-Abschnitt ohne

²⁷ Tadas Klimas and Jūratė Vaičiukaitė, The Law of Recitals in the European Community Legislation, 15 ILSA Journal of International & Comparative Law, 1 (2008).

²⁸ Monsanto ECJ Judgment *supra* note 12, paragraph 45

Angabe einer Funktion enthält keine *Lehre zum technischen Handeln* und stellt deshalb keine patentierbare Erfindung dar" (A simple DNA-segment without indication of a function does not contain a *technical teaching* and is therefore not a patentable invention). This means that a mere DNA sequence does not constitute an invention unless a function is given to the sequence. In other words, a DNA without this function is essentially excluded from patent eligibility as a natural phenomenon. This is the same approach argued by the Department of Justice with respect to the *Myriad* case.²⁹ In order to qualify as an invention, a "function," rather than a mere presence must be shown.

While the ECJ did not distinguish the function under Recital 23 and the function under Recital 24, it is not clear from the Directive whether the function in both Recitals is the same. Recital 23 discusses the function in context of patent eligibility while Recital 24 discusses the function in context of industrial application, a condition of patentability distinct from patent eligibility. Recital 24 furthermore provides two options to support the industrial application of a DNA sequence, (1) a disclosure to specify a protein or part of a protein that is produced by the DNA sequence or (2) a disclosure of a function that the DNA performs. However, ECJ did not pay any attention to the first option.

So what is meant by the term "function"? Unfortunately, ECJ did not give a clear answer. Recital 23 does not give any explanation of the function. Recital 24 at least gives an explanation that the func-

tion is what is to be described in the specification to support industrial application. Because the ECJ seems to assume that the functions in these Recitals are the same, the term "function" in "indication of a function" in Recital 23 should be understood as identical to the term "function" to support "industrial application."³⁰ As pre-*Bilski* U.S. courts use the utility requirement to limit the patent eligibility,³¹ the ECJ used industrial application requirement, which is the European equivalent of the utility requirement to limit the patentability, although the scope of patent eligibility under EPC and EU Directive must be limited to fields of technology unlike U.S. patent eligibility.

Recital 22 further specifies, *where* said indication of the industrial application (that is, function) has to be present/positioned in the application, namely in the specification (and not the claims). As will be explained further below, the ECJ adopted its interpretation while heavily relying on the "technical information" wording in the Dutch and English version. However, the technical information has nothing to do with industrial application. The wording of the Directive is inconsistent and confusing because it requires industrial applicability, a condition of patentability, before the presence of an invention, *i.e.* patent eligibility (technical teaching) can be acknowledged. Also, it is improper for ECJ to mix a formal requirement: a disclosure of the function in the specification, and a substantive requirement: patent eligibility into the same rules.

In addition, the ECJ introduced a lot of uncertainty in the interpretation of Article

²⁹ *Supra* note 1.

³⁰ See Straus: Produktpatente auf DNA-Sequenzen - Eine aktuelle Herausforderung des Patentrechts GRUR 2001, 1016, 1018

³¹ *In re Alappat*, 33 F.3d 1526, 31 USPQ 1545 (Fed. Cir. 1994); *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 47 USPQ2d 1596 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093, 119 S. Ct. 851, 142 L. Ed. 2d 704 (1999)

5(3) with respect to its applicability to non-human genes. The language in Article 5(1) and (2) makes it clear that the Article *only* relates to an element including a full or partial sequence of gene isolated from a human body or an element produced by a technical process to have the same structure of the isolated element of a human body.³² Accordingly, one may read "a sequence or a partial sequence of a gene" in Article 5(3) to include only a sequence that is isolated from a human body or produced by a technical process to have the same structure of the isolated sequence. If this interpretation is correct, since the '090 patent has nothing to do with a human DNA sequence, the ECJ was incorrect to rely on Article 5(3) in order to support its function-limited scope of protection.

This interpretation is supported by the German legislator's interpretation of Article 5(3). In revising the German Patent Law ("PatG") to implement the Directive, the legislator added Section 1a of PatG in order to implement Article 5 of the Directive. They made the same mistake in importing the patentability requirement into the scope of protection because this new section introduced an additional patentability requirement, a description requirement for the claims with respect to gene patents: "when the invention is a sequence of a gene, the composition of which is identical to the composition of a natural sequence of a *human gene*, the use thereof, for which the

industrial application is concretely described in the specification according to § 1a (3) of PatG, has to be included into the patent claim."³³ (emphasis added) Because of this requirement to include the use or function of human gene patents into the claims, German courts will have to apply a similar function-limited scope of protection for gene patents.³⁴ Nevertheless, this restricted patent scope would only apply to a claim directed a DNA sequence from a human gene, because the PatG makes clear that this additional claim limitation only applies to a DNA sequence of a human gene.

Because neither Article 5(3) of the Directive nor Section 1a (3) PatG expressly include an express limitation with respect to DNA sequences, contrary to the express limitations in Article 5(1) and (2) and Section 1a (1) (2) and (4) PatG, it seems possible to adopt the ECJ's interpretation to apply the additional requirement to *all* genes. Therefore, the ECJ's interpretation introduced a lot of uncertainty whether the additional claim limitation requirement should apply to a DNA sequence of non human genes such as a plant.

Further, there is no basis in the Directive for justifying the ECJ's importation of patentability rules into the analysis of the scope of protection. As will be discussed below, this importation introduces a lot of uncertainty not only to patent scope but also patentability with respect to DNA sequence patents.

³² Article 5(1), *supra* note 2

³³ German Patent Act (PatG), Section 1a(4). For a discussion of this additional requirement, see Jan Krauss, (Die Effekte der Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen auf die deutsche Praxis im Bereich dieser Erfindungen) Mitt. 11/2005, page 491, point 2.2

³⁴ Concurring with the ECJ: *Tilman* GRUR 2004, 561, 564 as "hybrid compound protection", but in relation to human sequences and the biological function of the gene

4. Proper Interpretation of Article 9 and Infringement Analysis

Despite its incomplete analysis and improper reliance on Article 5(3), the ECJ arrived at the correct result that - according to the Directive - the availability of a patent protection for a DNA sequence in a biological material should depend on the disclosure of the function as performed by the DNA.³⁵

It was actually unnecessary for the ECJ to import the patentability rule into the rule to determine the scope of protection, resulting in a special rule for the protection of DNA sequence patents. Had the ECJ simply properly interpreted the wordings of both the claims in the '090 patent and Article 9 of the Directive, the ECJ would have reached the same conclusion of non-infringement without introducing a lot of uncertainty.

The Court of The Hague referred a question only with respect to the scope of Claim 6 in the '090 patent.³⁶ Claim 6 depends on Claim 3 that further depends on Claim 1.³⁷ The preamble of Claim 1 reads: "an isolated DNA sequence encoding for an EPSPS enzyme. Therefore, the wording of Claim 6 is directed to a *specific* chemical substance consisting of a nucleic acid encoding the EPSPS enzyme. Because the claim requires the DNA sequence to be isolated from a biological material, this molecule cannot have a *biological* function. The isolated molecule is removed from the chromosome of the plant, and merely consists of the bases

encoding for the EPSPS enzyme, *i.e.* is a single "short" chemical compound. Thus, the claim does not literally cover *any* DNA-molecule when it is not contained in the chromosome where it can perform a biological function.³⁸ Since the isolated DNA sequence such as one in *Monsanto* has neither a biological function nor - outside of in vitro uses - the function described in the specification, the ECJ's interpretation casts a doubt whether patent protection is available for isolated DNA sequence is despite of the clear endorsement of patentability under Article 3 Paragraph 2 of the Directive except for a DNA sequence which has a diagnostic use or a use as a primer in vitro reaction.

Obviously, the Directive was drafted to acknowledge the double nature of DNA as a chemical compound *and* as a carrier of information.³⁹ This is one reason for the extension of the protection under Article 9, adding additional scope to the otherwise very limited protection of an isolated DNA compound as such, so that the compound claim covers all materials (and thus is extended), in which the claimed compound (that is, the DNA-sequence) is incorporated.⁴⁰ Because of the added protection, the whole chromosome of an organism (containing the respective DNA-sequence), and even an organism as such could be protected by such a claim. In order to limit the expansive scope of protection, Article 9 adds a condition for the additional protection: the genetic informa-

35 *Monsanto* ECJ Judgment *supra* note 12, paragraph 44.

36 *Monsanto* ECJ Judgment *supra* note 12, paragraph 32, (2).

37 For these claims, see *supra* note 6.

38 As correctly concluded by Justice Pumfrey in the parallel UK-proceedings, *Monsanto vs Cargill* [2007] EWHC 2257 (Pat).

39 See, for example, *Tilman* GRUR 2004, 561, 562

40 See, for example, *Krauss*, *supra* note 33, page 494, point 2.6

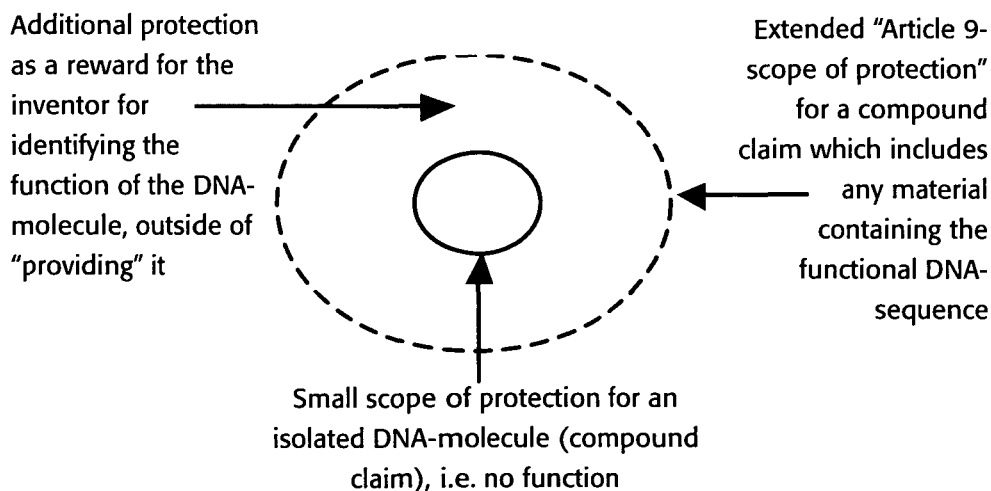
tion as introduced in the biological material has to perform its function (which supports industrial applicability).

The following simple diagram shall depict the relationship between the literal scope of an isolated DNA sequence and its extended scope of protection under Article 9:

When prosecuting patents, patent attorneys frequently have to deal with a very similar problem resulting from the double-nature of DNA. Patent examiners usually reject all patent claims that are directed to DNA-sequences, if the claims include an "open" transition term (e.g., "comprising") in contrast to a "closed" transition term ("consisting of"). In order to overcome this rejection, the examiners almost always demand to add the term "isolated" to DNA sequence claims in order to prevent a claim to cover "in situ" DNA-sequences. Therefore, Article 9 should not be read to prohibit an absolute compound protection for DNA-sequences (as natural substances). If a claim is properly interpreted, Article 9 should be read to actually extend the

scope of a chemical compound in order to compensate for the scope of the isolated compound that is actually very limited.

In summary, when the patent claim at issue is properly interpreted and Article 9 is correctly interpreted, the soybean meal in *Monsanto* as imported indeed does not infringe the claim. A claim directed to an isolated DNA sequence, i.e., a chemical compound does not literally cover the DNA sequence contained in the soybean meal because the sequence is not isolated from the chromosome in the meal. Because the DNA sequence in the imported soybean meal does (and can) not perform the function disclosed in the specification, the additional protection under Article 9 is not available for the meal. Whether the soybean meal falls into the definition under Article 2 (1)a of the Directive because the meal is no longer capable of reproducing itself or being reproduced in a biological system as required in the definition.⁴¹ Thus, the ECJ could have rejected the additional protection for this reason. Therefore, although



⁴¹ Joseph Straus, *The Scope of Protection Conferred by European Patents on Transgenic Plants and on Methods for Their Production*, Festschrift for Marianne Levin 643, 647 (2008). Prof. Straus gives a further clarification for the requirement of performing the function: A product meets the requirement if the product is used because of the function resulting from the genetic information carried by the DNA.

the ECJ made a mistake in relying on Article 5(3) to *limit* the scope of protection under Article 9, the Court was correct in limiting the additional protection by the function and finding that there was no infringement.

It is likely that ECJ's adoption of the restrictive protection scope for gene patents is a response to the political pressure coming from European politics. As acknowledged in Recital 22, gene patenting has been controversial and continues to be controversial, even after the implementation of the Directive in nearly all EU-member states. In fact, the scope of protection for a DNA-sequence has been one of the most frequently debated issues. As these claims provide absolute protection as a chemical compound, the alleged "overcompensation" derived from such protection was heavily criticized as exceeding the contribution made by the inventor.⁴² However, as discussed, this argument seems to be based on an improper interpretation of claims directed to an isolated DNA sequence.

In essence, the special rule that the ECJ and Advocate General, Paolo Mengozzi adopted is in line with the interpretation of Article 9 of the Directive advanced by German patent scholars. These scholars proposed to limit the scope of protection by the function as specified in the description of the patent specification.⁴³ Nevertheless, all these critics seemed to have overlooked that there can be a "peaceful coexistence" in case of the

scope of protection for a claim directed to an isolated DNA sequence consisting of a) the literal scope of the "actual invention" for identifying and producing a DNA sequence *plus* b) the extended scope as the "reward" for identifying a function *i.e.*, the actual industrial applicability for the DNA sequence.

The ECJ was of course aware of the chemical/information carrier double nature of a DNA sequence, and thus adopted the function-limited protection scope. However, the interpretation of Article 9 by the ECJ was more expansive than what was proposed by the German patent scholars because the scholars discussed the function-limited protection scope only with respect to human DNA sequences.⁴⁴ The function-limited scope proposed by a German scholar covers the functions disclosed in the description of the specification as well as functions that obviously relate to the disclosed functions.⁴⁵ In contrast, in *Monsanto*, the ECJ opinion can be read to apply the function-limited scope of protection to *all* DNA-sequences, irrespective of whether they are of human origin, are used for encoding a protein, or are used as a (diagnostic) "tool".

At least, ECJ provided a clarification regarding the interpretation of Article 9 in making clear that the function required for patent protection is the function specified in the specification for supporting the industrial application.⁴⁶ Before *Monsanto*, there was a debate in the patent community whether a function as recited in

⁴² e.g. G. König, in: Festschr. f. Reimar König, 2003, p. 267

⁴³ See, e.g., Meyer-Dulheuer, GRUR 2000, 181, Nieder, Mitt 2001, 99; Nieder, Mitt 2001, 238; Feuerlein, GRUR 2001, 563, Tilman GRUR 2004, 561

⁴⁴ Tilman GRUR 2004, 561, 564

⁴⁵ This concept to interpret the scope of protection seems interestingly similar to the old "inventive contribution" concept that the BGH frequently used to determine the scope of patented inventions before the introduction of amendments regarding the scope of protection in 1968.

⁴⁶ *Monsanto* ECJ Judgment *supra* note 12, paragraph 45.

the Directive could relate to the biological function of the DNA sequence.⁴⁷ The ECJ put an end to this debate by stating that function is not the "biological function" of a DNA, but is the function of a DNA described in the specification to support industrial application.

It is interesting to note that the ECJ paid such a special attention to the term "technical information" regarding the function in Recital 23 and focused its analysis on the information as "stored" in the DNA. As a result, since the DNA has to be "read out" or "implemented" to perform its function for a patent protection, ECJ's "function limited protection scope" can even be described as "information-bound compound protection".

This requirement of implementing information by introducing into a biological material parallels to a similar requirement for inventions which are related to carriers of information in other fields of technology, namely computer-implemented software inventions. Like an isolated DNA sequence, software in the abstract detached from an activating medium is mere information and does not qualify for patent protection because it does not have a technical character⁴⁸ or does not relate to any technical field.⁴⁹ Such software will have a technical character only if it is read out or implemented

in an activating medium such as a machine readable memory and a hardware resource to provide a function to solve a technical problem. Therefore, the EPC requires inventors to include a disclosure of the technical function into the specification⁵⁰ and the essential technical features into the claims.⁵¹ Although arguably not identical, the German approach is quite similar.⁵²

The US patent system applies the same requirement because software in the abstract is mere information and thus excluded from patent eligibility as an abstract idea.⁵³ This is because software in the abstract cannot be inserted into a machine or downloaded from Internet unless it is expressed as a computer-readable copy and thus does not perform any function.⁵⁴ Unless the information represented in the software is implemented and applied to a specific field of technology and addresses a need in the technical field, it remains an abstract idea and thus is not patentable.⁵⁵

With respect to the scope of protection, software in the abstract does not enjoy any patent protection because it does not have any function. Along these lines, the US Supreme Court made it clear that one cannot commit contributory infringement with respect to software in the abstract, because the software does not constitute a

47 See, for example EPO case law in re ICOS, OJ EPO 6/2002, page 293, T 0898/05 of 7 July 2006, referring to e.g. T 870/04 of 11 May 2005

48 EPO Examination Guidelines ("EPC Rule") Chapter IV, Part C, 1.2(ii).

49 Implementation Regulations to the Convention on the Grant of European Patents, ("EPC Rule") Rule 42(1)(a).

50 Rule 42(1)(c) EPC

51 Rule 43(1) EPC

52 BGH, GRUR 2004, 667 – *Elektronischer Zahlungsverkehr*; GRUR 2009, 479 – *Steuerungseinrichtung für Untersuchungsmodalitäten*

53 *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

54 *Microsoft Corp. v. AT&T Corp.* 549 U.S. 991 (2006).

55 *Research Corp. Techs. v. Microsoft Corp.*, 2010 U.S. App. LEXIS 24984 (Fed. Cir. Dec. 8, 2010)

component under 35 U.S.C. §271(f), even if such software is incorporated as part of a machine or process claim.⁵⁶

In contrast, as noted above, an isolated DNA *in vitro* may enjoy a protection as a chemical compound with a scope that is independent from its function, but, as stated above, such protection usually in practice is very limited or even worthless.

V. Possible Impact of Monsanto on the Patentability of Gene Patents

In *Monsanto*, the ECJ primarily decided on infringement issues with respect to the scope of patent protection for a gene patent under Article 9 of the Directive. Therefore, in theory the decision should not result in any impact on patentability of DNA sequence patents. Nevertheless, in practice it is very likely that the decision will indeed have a quite significant impact on the patentability of DNA sequence patents. This is because the ECJ extensively discussed the conditions of patentability with respect to DNA sequence patents. Such impact is also inevitable throughout EU member states since the ECJ emphasized the necessity to further enhance harmonization of patent protection, and rejected any flexibility for allowing EU member states to adopt an absolute compound protection for a claim directing to a DNA sequence.⁵⁷

The legislators of all EU member states must take into account of the impact of

Monsanto and make necessary amendments to their national patent law because Article 1(1) of the Directive requires them to meet the obligations under the Directive. They may read *Monsanto* to require amendments to national patent laws with respect to the scope of patent eligibility and the proper drafting of claims. Currently, an applicant can obtain a patent from the European Patent Office with a claim directed to a DNA sequence without a function limitation. In spite of no functional limitation in the claim term, such claim will be interpreted to have a function limited scope of protection under *Monsanto*. Article 69 of the EPC requires the extent of the patent protection to be determined by the claims although the specification and drawings shall be used for interpreting the claims.⁵⁸ Therefore, the ECJ's function-limited scope of protection is in serious conflict with this fundamental principle because it requires the patent offices and courts to read a limitation into the claims based on a function as described in the specification. In order to avoid this conflict, national legislators may introduce an amendment to their national patent laws in order to introduce said function-limitation into the claim when a claim is directed to a DNA sequence.

Such requirement to include such limitation will lead to a multitude of legal and technical uncertainties in patent practice in EU member states, including Germany. As discussed above, the German legisla-

⁵⁶ *Supra* note 54, Microsoft Corp.

⁵⁷ *Monsanto* ECJ Judgment *supra* note 12, paragraph 63.

⁵⁸ Article 69(1) EPC

tor revised PatG and included §1a PatG.⁵⁹ However, the requirements under the German PatG are different from the ECJ requirements under *Monsanto*, as the requirements under *Monsanto* apply to any DNA sequence, *i.e.* not only to a DNA sequence from a human gene⁶⁰ when the DNA has the composition identical to the composition of a natural sequence of a human gene.⁶¹ This additional requirement for claim drafting is inconsistent with Article 5 (3) of the Directive because the article only requires a disclosure of the industrial application, *i.e.*, the function of a sequence or partial sequence of a human gene in the patent specification (not in claims). However, it is likely that the German legislator imported the scope of protection requirement into patentability as the ECJ had done in *Monsanto*.

Any such requirement to include a functional limitation into the claim would also have a significant impact on the patent practice under the EPC because EPC requires using the Directive and its legislative history as supplemental means for interpreting the EPC rules relating to patent applications for biotechnological inventions.⁶² Therefore, if *Monsanto* is understood to interpret the Directive in a way to require an amendment to the national patent laws in EU member states, the EPC has to be amended, too. This would have an effect far beyond the EU because many non-EU member states are members of EPC.

Furthermore, the ECJ in *Monsanto* can be read to reject the German scholar's proposal which always interprets a claim to be limited by the description of the specification if a claim is directed to a DNA sequence.⁶³ Such a special rule of claim interpretation is in conflict not only with the fundamental rule of the scope of protection under Art. 69 EPC, but also with the national case-law relating to the interpretation claims in national patents, and would introduce a lot of legal uncertainty. As discussed above, if a DNA sequence claim is properly interpreted, such amendments are not at all necessary. Even without such limitation, the literal scope of a DNA sequence claim is very limited even if an "absolute" compound protection is available. Only the extension of such claim to a biological material should be limited by the function described in the specification. These two parts of the scope can exist in parallel without causing any problems with current patent law doctrines, and even would not conflict with an analysis of the scope based on the doctrine of equivalence.

In addition, it is important to note that the ECJ decided that its decision to preclude an absolute compound for DNA sequences also applies to patents that were issued before the effective date of the Directive.⁶⁴ Therefore, regardless of the date of grant, *all* patent owners can "suddenly" no longer enforce a DNA-sequence patent unless the sequence performs the

⁵⁹ §1a PatG.

⁶⁰ §1a (2) PatG

⁶¹ §1a (4) PatG

⁶² As recently done so, for example, in the decision of the Enlarged Board of Appeals at the EPO, G1/08 and as stated in Rule 26(1) EPC

⁶³ As apparently proposed by *Tilman*, footnote 17

⁶⁴ *Monsanto* ECJ Judgment *supra* note 12, paragraph 66.

function disclosed to support industrial applicability. In an infringement proceeding, this new scope of protection creates a number of issues, such as, what is the function, and whether the patented DNA can perform the function. To add to the confusion, the Court of The Hague made it clear that a DNA sequence does not need to perform its function continuously.⁶⁵ How will the courts now distinguish a DNA sequence which temporarily stops performing its function from a sequence which permanently stops performing its function? The function limited protection scope also introduces uncertainty in patent validity because accused infringers may challenge the validity arguing that a claim directed to an isolated DNA sequence without a functional limitation is invalid under *Monsanto*. In order to overcome this challenge, patent owners may need to amend the claim scope by introducing a limitation of the function that the DNA sequence performs. Regardless of possible litigation, patent owners may feel it is necessary to make such an amendment to avoid validity challenges.

Finally, applicants should now expect a more rigorous examination, if their applications include a claim directed to a DNA sequence. In order to meet both patent eligibility and industrial application standard, it is advisable to include a broader disclosure of the function(s) of a DNA sequence, and even data to support the function.⁶⁶ Such disclosure is helpful for overcoming a rejection if the EPO and/or national patent offices in the EU member

states decide to require introducing the function(s) into the claims as a limitation. Even if a patent has already been granted to claims which do not include a functional limitation, *Monsanto* already limits the scope of protection of these claims to the function that is described in the specification in order to support industrial applicability. This function bound protection scope applies to *all* DNA-sequences regardless of its origin (human body or not) as well as regardless of its use (as a research tool or for encoding a protein.)

VI. Conclusions

After all, *Monsanto* certainly is a very extreme case for "testing" absolute compound protection where a practical threat from the infringement is far from imminent. The claimed DNA sequence is "dead" (non-functional) as long as it remains in the soybean meal. Therefore, alleged infringers in practice would not have been able to enjoy the benefit of the invention unless they would isolate the patented DNA sequence from the meal, and transfer it into a different biological material in which the sequence performs the function. Despite the exceptional nature of the dispute, *Monsanto* gave the ECJ an opportunity to develop a special rule which now is applicable to all claims directed to any DNA sequence. Because of the ECJ's improper reliance on the part of the Directive relating to patentability to support its restricted protection scope, the interpretation may result in significant

⁶⁵ Monsanto ECJ Judgment *supra* note 12, paragraph 28

⁶⁶ And not to rely on the choice as provided by Recital 24

impacts not only on the scope of protection but also on the patentability of a claim directed to a DNA sequence. The impacts may further lead to amendments to national patent laws not only in the EU but also EPC member states. Patent owners and applicants are now required to

closely follow the case law in national courts in EC member states, as well as the EPO, and have to be prepared to face additional requirements that may result from *Monsanto*, if their patents or patent applications include a claim directed to a DNA sequence.